

# State of Maryland

## Department of Health and Mental Hygiene

Parris N. Glendening, Governor - Martin P. Wasserman, M.D., J.D., Secretary

Office of Food Protection and Consumer Health Services  
Alan L. Taylor, R.S., Director

9307 '99 APR 21 10:35

April 20, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

[Docket No. 98P-0504]

Subject: Performance Standard for *Vibrio Vulnificus*

Dear Sirs:

We are responding to your request for comments regarding a petition by the Center for Science in the Public Interest (CPSI) to the U.S. Food and Drug Administration. This petition is requesting that the FDA take regulatory action to establish a performance standard of "nondetectable" for *Vibrio vulnificus* in molluscan shellfish intended for raw consumption and harvested from waters that have been linked to a case of shellfish-borne illness from this organism.

This Office wishes to respond to the issues in this petition in two areas. First, we want to address the petition for the establishment of a performance standard in regulation. Secondly, we want to address the assertion made in the petition that a death from *V. vulnificus* can be attributed to shellfish harvested from Maryland waters.

### **CPSI's petition for a performance standard for *Vibrio vulnificus***

As both FDA and CPSI recognize, a standard of "nondetectable" would require post-harvest treatment of oysters from waters that have been linked to illnesses or deaths from *V. vulnificus*. Since there is currently only one approved process for reducing *V. vulnificus*, the AmeriPure Process, this raises the following questions.

1. Is the AmeriPure process reliable, has it been independently tested, and, if not, are the results of testing available for independent review?

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FAX 410-333-8931 - TDD for Disabled, Maryland Relay Service, 1-800-735-2258

98P-0504

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2. If the AmeriPure process proves not to be reliable, are there any other methods for reducing the amount of *V. vulnificus* or *V. parahaemolyticus* in shellstock? Irradiation has not been approved and hydrostatic pressure is being developed. If a standard of "nondetectable" is set prior to having a proven method and a choice of methods for meeting this standard, industry is gravely impacted as are the regulatory agencies.
3. Since the oyster treated by the AmeriPure process is no longer a living organism are there other pathogenic bacteria, such as *C. botulinum*, that pose a risk in the heat treated, banded shellstock?
4. No small dealer will have access to this patented technology. If this cannot be employed readily by a large segment of the industry, are there other, more readily usable methods that can lower the public health risk?

**Incorrect assertion of a *V. Vulnificus* illness due to Maryland shellfish**

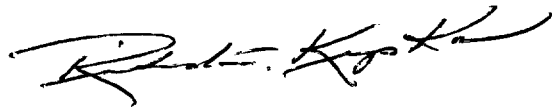
CPSI alleges in its petition (pgs. 8-9) that a death due to *Vibrio vulnificus* in shellfish harvested in Maryland waters may have occurred. An investigation conducted by the Maryland Department of Health and Mental Hygiene and the USFDA found that the oysters harvested in Maryland did not cause this death.

In April of 1996, a woman in California ate raw shellstock, 3 hard clams from the Indian River in Florida, and 3 oysters that, according to the tag at the restaurant, were harvested from the Nanticoke River in Maryland. Investigation revealed that a Florida shipper purchased the oysters from a Maryland dealer and transported them to Florida. From there the oysters were then shipped to California. The Maryland oysters from that area were tested in both California and Maryland and no *V. vulnificus* was found. *V. vulnificus* was found in the Florida clams. Based on these samples and a review of the water temperature and salinity of the harvest waters, Maryland oysters were not implicated in this illness.

There has not been a *V. vulnificus* associated death or illness from molluscan shellfish harvested or wet stored in Maryland waters. Therefore, if FDA decides to adopt a case-based performance standard for *V. vulnificus*, Maryland should be **exempt** from this requirement.

Thank you in advance for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard J. Kropka", with a stylized flourish at the end.

Richard J. Kropka, Chief  
Division of Food Control

**1 From** **Date** 4/20/99

**Sender's Name** ERIN BUTLER **Phone** 410 767-8404

**Company** DHMH OFFICE OF Food Protection

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**Company** Food and Drug Administration

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